UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

GOVERNMENT OF GUAM RETIREMENT FUND, on Behalf of Itself and all Others Similarly Situated,

Plaintiff,

v.

INVACARE CORPORATION, *et. al.*,

Defendants.

Case No. 1:13-cv-1165-CAB

CLASS ACTION

NOTICE OF RECENT AUTHORITY IN FURTHER SUPPORT OF LEAD PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

Lead Plaintiff respectfully submits this Notice of Recent Authority to call the Court's attention to the recent decision by the United States District Court for the Northern District of California in *Denis Mulligan v. Impax Labs., Inc., et al.*, No. C-13-1037 EMC (N.D. Cal. April 18, 2014) ("*Impax*"), a copy of which is attached hereto as Exhibit A. *Impax* involves strikingly similar facts to the instant action, and the *Impax* court's decision and reasoning provide strong support for denying Defendants' motion to dismiss here.

Impax, like this action, concerns statements made by a highly-regulated medical company and its senior executives regarding the company's purported compliance with FDA regulations, and defendants' failure to disclose the truth about the company's cGMP, record-keeping and

quality control problems in the face of repeated warnings by the FDA. Like Invacare, the defendant company in *Impax* was repeatedly cited and warned by the FDA for pervasive, serious and recurring cGMP and record-keeping deficiencies. As here, defendants in *Impax* challenged the sufficiency of plaintiffs' allegations for the federal securities fraud claims, specifically, the elements of scienter and materiality.[1] The *Impax* court denied defendants' motion to dismiss, holding that both defendants' scienter and the materiality of their regulatory compliance statements were sufficiently alleged.

First, the *Impax* court rejected defendants' scienter arguments based on the long-standing, recurring and pervasive compliance problems – "many of which were identified by the FDA on more than one occasion." *Impax* at 20. In particular, the *Impax* court found that the company's receipt of repeated adverse inspectional reports on FDA Forms 483 "from one year to another gives rise to a reasonable inference that problems were not adequately addressed or remediated." *Impax* at 20-21 n.1. The court also found a strong inference of scienter supported by the accounts of numerous former employees who provided "consistent accounts of the conditions, practices, and procedures of Impax," and who confirmed that the defendants failed to undertake any serious remediation efforts and, instead, "sought to hide issues from the FDA" through a "practice and culture of implementing and reversing corrective measures" because they "were primarily concerned with wrapping up paperwork and closing investigations, rather than actually fixing problems." *Id*. at 12, 14, 19, 23. Substantially similar allegations and eyewitness accounts are included in Lead Plaintiff's 132-page Amended Complaint here, including nearly seventeen years of FDA warnings concerning the same regulations and the same misconduct, and the accounts of numerous former long-time Invacare employees confirming that "nothing ever really changed" at Invacare, and management promoted a deeply-ingrained culture of contempt for the FDA and simply created a "smokescreen" to try to appease the FDA.

[1] Defendants in *Impax* also contested the element of falsity, which Defendants here do not directly challenge. Lead Plaintiff's Opposition To Defendants' Motion To Dismiss The Amended Complaint For Violations Of The Federal Securities Laws (ECF No. 37) at 7.

Second, the *Impax* court found that even in the absence of direct evidence of defendants' scienter, plaintiffs had adequately alleged the company's senior executives had knowledge of the falsity of their regulatory compliance statements under the "core operations" inference. *Id.* at 32. The court reasoned that it was "'absurd'" to think that the CEO and CFO of a highly regulated company "would be unaware of the alleged substandard, non-compliant conditions pervading their company's manufacturing and quality divisions" – the "***heart***" of the company. *Id*. at 34 (emphasis added). The court found it "even more unlikely" that the defendants would be unaware of the problems "given the repeated Form 483s and the Warning Letter from the FDA," which are intended to inform top management of significant objectionable conditions. *Id*. Finally, the court noted "[a]n inference of scienter is strengthened by the allegation of pervasive and long standing problems which allegedly were covered up as a matter of policy at Impax." *Id*. Here, in addition to ample direct evidence of Defendants' scienter, Lead Plaintiff's Amended Complaint also provides similar, detailed allegations supporting a "core operations" inference.

Finally, the *Impax* court found that virtually all of defendants' statements of compliance and remediation efforts were material as a matter of law. The *Impax* court reasoned that "the challenged statements were allegedly made by Defendants at a time when one of their two manufacturing facilities had received significant warnings from the FDA. It is reasonable to believe that investors in . . . an industry where regulatory compliance . . . is essential[,] would find such an event disconcerting. This is especially the case when the very core of Impax's business – its manufacturing facilities – was in potential jeopardy." *Id*. at 31. Here, the facts are even more compelling, as Defendants' false statements occurred at a time when both of Invacare's primary manufacturing facilities – as well as its corporate headquarters – were subject to repeated citations and warnings by the FDA and imminent adverse action, which ultimately resulted in a Consent Decree requiring the Company to cease manufacturing and design operations at the Elyria locations that remains in effect to this day.

Dated: April 23, 2014

Respectfully submitted,

/s/ Benjamin Galdston

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CERTIFICATE OF SERVICE

A copy of the foregoing was filed electronically this 23rd day of April, 2014. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Benjamin Galdston